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United States Courts  
Southern District of Texas  
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JAN 04 2011



**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

**UNITED STATES OF AMERICA,**  
**ex rel. TERRI KING**  
**Plaintiff and Plaintiff-Relator,**

**V.**

**UNIVERSITY OF TEXAS HEALTH  
SCIENCE CENTER-HOUSTON;**

**Defendants.**

§ § § § §

H-11-018

CIVIL ACTION NO. \_\_\_\_\_

## JURY TRIAL DEMANDED

## ORIGINAL COMPLAINT

## I. JURISDICTION

1. This suit is instituted pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* Jurisdiction of this Court is invoked pursuant to 31 U.S.C. §§ 3730 (b), 3732(a) and 28 U.S.C. §§ 1331.

## II. NATURE OF CASE

2. This action is brought by Terri King (hereinafter 'King') on behalf of the United States of America to impose liability upon Defendant, University of Texas Health Science Center-Houston (hereinafter 'UTHSCH') for violations of 31 U.S.C. §§ 3729 *et seq.*

### III. PARTIES

3. Plaintiff-Relator King is a citizen of the United States and a resident of Houston, Texas.

4. Defendant, University of Texas Health Science Center-Houston, has its principal place of business in Houston, Texas. UTHSCH may be served with this lawsuit through its

registered agent, Texas Secretary of State/UCC Division, 1019 Brazos, Suite 505, Austin, Texas 78701.

#### IV.

#### STATEMENT OF FACTS

5. King is a former an Assistant Professor at UTHSCH. King attended the University of Texas-San Antonio from September of 1983 to May of 1985 with a major of Applied Mathematics. King received a Bachelor of Science degree from The University of Texas-Austin in Zoology in May of 1988. King received a Master of Science degree in Biostatistics and Epidemiology from Georgetown University in May of 1989. King went on to Johns Hopkins University where she obtained a Doctor of Philosophy in Human Genetics/Genetic Epidemiology in May of 1993. In September of 1993, King started a Post Doctoral Fellowship at the University of Texas-M.D. Anderson Cancer Center under the direction of Christopher I. Amos, Ph.D., which she completed in June of 1995. In 1996, King accepted a faculty position with the Department of Epidemiology at University of Texas-M.D. Anderson Cancer Center in Houston, Texas and held that position until 2001. From 1999 to 2001, she also served as Director of Pharmacogenetics and Epidemiology at Genometrix, Inc. in The Woodlands, Texas. In 1997, King became an Associate Member of the University of Texas Graduate School of Biomedical Sciences and continues to be so associated. King then accepted a position as Assistant Professor, Department of Internal Medicine, at the UTHSCH and served in that position until 2005. King then accepted a position as Assistant Professor, in the Department of Pediatrics at the UTHSCH and holds that position at this time. In 2007, King completed a clinical fellowship in Medical Genetics. She received Board Certification from the American Board of Medical Genetics as a Ph.D. Medical Geneticist. (Exhibit I; CV King)

6. While employed by the UTHSCH, King became aware of violations of ethical principles and regulatory mandates regarding human research that were being violated by Dr. Dianna M. Milewicz (hereinafter 'Milewicz'), a faculty member at UTHSCH. Generally, King became aware as a member of Milewicz' lab, that Milewicz was manipulating data related to her research that was funded by Federal grants so that the data would support her hypothesis. Milewicz then published her work based on false or manipulated data and used incorrect methodologies to interpret that data in order to publish findings supporting her hypothesis. These publications then allowed her to position herself as a leader in her field, thereby attracting more Federal research dollars to fund further research in her lab. King later learned, as a committee member of the UTHSCH Internal Review Board (IRB), that Milewicz was recruiting human subjects for her research without obtaining any written informed consent in compliance with both Federal regulations and internal UTHSCH policies. When King raised these issues with the appropriate officials within UTHSCH, she was subject to systematic and unrelenting retaliation within the institution finally resulting in her termination in June of 2010.

7. Prior to receiving Federal funds supporting research, the UTHSCH is required to agree to abide by the terms of the Federal Wide Assurance for the Protection of Human Subjects. (Ex. 2, FEDERAL WIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS; Ex. 3, UTHSCH Policy of Institutional Assurance.) UTHSCH has so agreed and continues to agree to abide by the FWA for the protection of Human Subjects. (FWA #00000667, expires 8/17/2013) When an institution such as UTHSCH becomes engaged in Federally-conducted or supported human subject research, UTHSCH and its Institutional Review Board (IRB), must comply with the Federal Policy for the Protection of Human Subjects. When human subject research at UTHSCH is supported by Federal funding, the UTHSCH must certify that it

will comply with all sub-parts of the Health and Human Services (hereinafter 'HHS') regulations found at Title 45 C.F.R. part 46, subparts A, B, C, and D) The Basic HHS Policy for the Protection of Human Research Subjects is found at 45 C.F.R.§46.103 sub part A. This Basic Policy requires that UTHSCH develop written procedures for ensuring prompt reporting of (i) any unanticipated problems involving risks to human subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval, to the UTHSCH IRB, appropriate institutional officials, and the department or agency head. (45 C.F.R. §46.103 (b)(5)) The Basic Policy requires that the UTHSCH IRB conduct continuing review of research conducted pursuant to this policy, including scientific misconduct, failure to properly consent subjects, and/or retaliation against "whistle blowers". These reviews by UTHSCH and/or its IRB must occur at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third-party observe the consent process and the research. (45 C.F.R. §46.109 (e)). The UTHSCH IRB must have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. (45 C.F.R. §46.113) No researcher for UTHSCH may involve a human being as a subject in research supported by Federal funds unless the researcher has obtained the legally effective informed consent of the subject, or the subject's legally authorized representative. (45 C.F.R.§46.116) Further, the FWA requires that all informed consent must be appropriately documented. (45 C.F.R. §46.117) These regulations prohibit expending federal funds on UTHSCH research unless the Federal Policy for the Protection of Human Subjects has been satisfied. (45 C.F.R. § 46.122 Use of Federal funds) Finally, the UTHSCH certified in its Federal Wide Assurance to the DHHS that

it would put in place protections for “whistleblowers” who made good faith reports of scientific misconduct. UTHSCH certified in exchange for the right to seek and accept federal funds for scientific research that it would protect whistleblowers from retaliation and take reasonable steps to protect their confidentiality as much as practicable. (45 C.F.R. § 93.300 (d) (e) and §93.108)

8. On or about March of 2001, King was hired to work in a lab being supervised by Dr. Dianna M. Milewicz, M.D., Ph.D., in the UTHSCH system. Milewicz was the principal Investigator in genetic research focusing on Thoracic Aortic Dissection. King, as a Statistician and Geneticist, was assigned duties regarding the management and analysis of data collected for Milewicz’ research. In 2004, King began to notice discrepancies in the data utilized by Milewicz. When she began to bring these discrepancies to the attention of Milewicz, Milewicz began a retaliatory campaign against King that began with the writing of a false and defamatory employee performance review regarding King. (Ex. 4; False Performance Evaluation and King’s Responses) King also witnessed other employees in the lab subjected to similar harassment and retaliation when they presented data that was inconsistent with Milewicz’ theories and hypothesis regarding the genetic component related to Thoracic Dissection. King witnessed graduate students who were threatened by Milewicz with poor grades, bad references, or even interference with their immigration status when they presented data that was inconsistent with Milewicz’s hypothesis, questioned Milewicz’s conclusions or interpretation of the genetic data supporting Milewicz’s work. King witnessed retaliation against lab employees who logged data that was inconsistent with Milewicz’ hypothesis or further questioned or refused to change the data so as to support Milewicz’ hypothesis. King witnessed the manipulation of data by Milewicz’s lab employees who were intimidated by Milewicz’s harassment and retaliation leveled against anyone who dared to make findings or report data that was inconsistent with Milewicz’s

hypothesis regarding the identification of the genetic component associated with an increased risk of aortic dissection.

9. King successfully defended her work performance in response to Milewicz's unfounded criticism written in King's 2005 performance review, but the harassment of King did not stop there. Milewicz did everything she could to make King's working life difficult and suffocate King's attempts to perform scholarly activities that would advance her goal of obtaining a position of full time tenured faculty at UTHSCH. By August of 2005, the situation had become hopelessly bitter and intolerable for King working in Milewicz' lab. King sought a solution from Dr. Bruce Kone (hereinafter 'Kone') who was head of the department. Kone consulted with the Dean of the medical school and members of the Pediatrics department and suggested that King transfer from Milewicz's lab to Pediatrics, writing to King on August 30, 2005. "I don't know what your initial reaction will be, but I think this is wonderful news for you----a true home, active mentoring, a lot more protection, and a lot more investment in your career. I have no way to protect you in my department or to provide the type of environment you need." (Ex. 5, Email, August 30, 2005, Kone to King)

10. On or about April 2, 2007, King was contacted by UTHSCH Human Resources Department. UTHSCH Human Resources requested her participation as a witness in a harassment complaint against Milewicz. (Ex. 6, April 2, 2007 email, Rayburn to King) King participated in that investigation. At the end of her interview regarding that investigation, the Human Resources Representative of UTHSCH asked King if there were any other issues that she wished to raise. At that time, King did not raise any issues. On or about April 23, 2007, King contacted the Human Resources Representative saying that she had concerns that were not directly related to the original harassment claim. (Ex. 7, email chain April 23, 2007 to April 24,

2007) The UTHSCH EEOC ('Equal Employment Opportunity Commission') advisor, J.T. Rayburn (hereinafter 'Rayburn'), agreed to meet with King on May 4, 2007 at 9:30 a.m. In that meeting, King disclosed that she had information about the hostile working environment and its effect on the integrity of the lab data being used by Milewicz. King indicated that she had witnessed specific examples of research misconduct including fabrication and/or falsification of data by Milewicz, or at the insistence of Milewicz. King informed Rayburn of an incident where angry employees terminated their employment in Milewicz' lab as a direct result of the hostile working environment and then destroyed the Federally funded data as they departed the premises.

11. At the conclusion of King's disclosure to Rayburn he told her that he needed to consult with his Supervisor regarding the next steps. Later that day, Rayburn informed King that he had consulted with the UTHSCH Vice President of Human Resources regarding her statements. They advised her to contact Karen Parsons (hereinafter 'Parsons'), then the Director of Institutional Compliance (Currently the Assistant Vice President & Chief Compliance Officer). (Ex. 8a. May 4 2007 email, Rayburn to King)

12. On or about May 4, 2007, King contacted Parsons and agreed to a face-to-face meeting. In that meeting, King described to Parsons the significant level of intimidation and harassment Milewicz used to control her lab personnel. King told Parsons that Milewicz' abuse of her lab personnel had led to the destruction of research data and the falsification and manipulation of data by lab staff who feared retaliation and harassment from Milewicz if they did not agree to Milewicz' demands to produce results that agreed with Milewicz' hypothesis. King explained that what she had witnessed in Milewicz' lab had led her to have grave concerns about data integrity. King described to Parsons how Milewicz would harass and abuse any lab employee or grad student that presented data that might be inconsistent with Milewicz' stated

hypothesis. In many instances, King told Parsons that the lab staff would falsify lab data either to avoid the wrath of Milewicz, or after having been abused by Milewicz, for presenting data that was inconsistent with Milewicz's research goals. King provided names of witnesses to this data falsification, data destruction and other instances of research misconduct that were caused by Milewicz's harassment and intimidation tactics. (Ex. 8b; May 6, 2007, email chain, King and Parsons) King had another meeting with Parsons on or about May 14, 2007. In that meeting King provided Parsons seven (7) additional names of people who had information related to various aspects of Milewicz's scientific misconduct. She also provided two (2) names of people who had information about Milewicz's fiscal mismanagement in her lab. (Ex. 9; May 16, 2007, email, King to Parsons) On or about May 24, 2007, King met again with Parsons and provided more specifics about Milewicz's harassment and intimidation leading to compromised data integrity. (Ex. 10, May 24, 2007, email, King to Parsons) In that meeting, King provided the names of four (4) lab employees and identified information as to a 5<sup>th</sup> graduate student, Yuhua Qi, who had experienced Milewicz's harassment and intimidation. King explained the circumstances of Milewicz's harassment of Qi and how the hostile working environment created by Milewicz led to compromised data integrity in Milewicz's lab. King reported to Parsons that when Milewicz was told by her lab personnel that the data was not supportive of her hypothesis, Milewicz's stock reply was to tell them to "make it work". King explained to Parsons that any lab employee that did not find a way to change or manipulate the data and "make it work," was subjected to relentless harassment from Milewicz. King knew this from firsthand experience and from observing others in the lab. King had specifically told Milewicz that her lab had problems with quality control measures and that as such, Milewicz's data integrity was compromised. Milewicz replied, "we never had any problems in this lab with data until you started these ridiculous



audits". It was after King challenged the integrity of Milewicz's lab data that Milewicz initiated her campaign of false accusations against King in a failed attempt to have King terminated. King clearly related these facts to Parsons so that the UTHSCH's Office of Compliance could properly conduct an investigation of Milewicz' harassment and resulting scientific misconduct. UTHSCH had a duty to investigate the information provided by King in the performance of its oversight responsibility as mandated by UTHSCH's Handbook of Operating Procedures and United States Department of Health and Human Services regulations. As noted above, the FWA plan agreed to by UTHSCH, as a condition of the acceptance of Federal funds, required that UTHSCH thoroughly investigate alleged scientific misconduct in research involving human subjects. (Ex. 11, UTHSCH HOOP Chapter 23.04 and Ex. 12, 42 C.F.R. Part 50, Subpart A DHHS Regulations; See also paragraph 7 above)

13. In the meeting of May 24, 2009 between Parsons and King, Parsons stated that Dr. Peter Davies (hereinafter 'Davies') would be charged with the responsibility of investigating the validity of King's allegations as part of the "initial phase" of the compliance process. The initial phase of the compliance process requires a designated compliance officer to review the allegations and determine whether or not an "official inquiry" of the allegations will be conducted. This phase is not unlike a probable cause hearing in a criminal case. The compliance officer is to initiate an official inquiry into alleged scientific misconduct if:

- A. There is sufficient evidence to warrant an inquiry;
- B. PHS (Public Health Service) and/or DHHS (Department of Health and Human Research) funds are involved in the alleged misconduct;
- C. The allegation falls within the PHS definition of scientific misconduct. (Ex. 11 HOOP Appendix C and Policy 23.04, Ex. 12, 42 C.F.R., Part 50, Sub-Part A);

The execution of this investigative protocol is required under UTHSCH's FWA agreement with the Federal Government and is a condition of receiving Federal funds to support human research.

In the meeting of May 24, 2007, Parsons told King that she was going to arrange an anonymous phone conference between King, Parsons and Davies, to discuss King's allegations. After the meeting, King expressed concerns about the objectivity of Davies because of a strong collaborative history with Milewicz. (Ex. 13, May 25, 2007, email, King to Parsons) King told Parsons that Davies had served on the thesis committee for a graduate student Yuhua Qi. Qi was one of the witnesses identified by King as having suffered retaliation from Milewicz because Qi's data was inconsistent with Milewicz's hypothesis. Milewicz had accused Qi of cheating and had tried to have her expelled. Qi had been subjected to threats of expulsion from graduate school and/or revocation of her student visa by Milewicz when her experiments did not support Milewicz's a prior hypothesis. King was present when Milewicz alleged in Qi's thesis committee that she had cheated in her coursework in graduate school including, suggesting that Qi's husband had actually completed all of Qi's assignments and course work. Davies was in attendance at this thesis meeting and was a member of the committee. Shortly after these incidents, Qi started producing results that supported Milewicz' hypothesis. She was allowed to defend her thesis and graduate and Milewicz withdrew her charges of cheating. Because of Davies' firsthand knowledge of these events, King asked that Davies be conflicted out of evaluating King's claims against Milewicz because he was a witness to an example of the harassment by Milewicz. (Ex. 13, id) Further, King expressed concerns to Parsons that her anonymity as the reportee of alleged scientific misconduct would be breached by Davies because of Davies' collaborative relationship with Milewicz. (Ex. 13, id) King also identified other executive members of the administration with conflicts. (Ex. 13, id)

14. A large portion of Milewicz's research at UTHSCH is federally funded through grants and other Federal Government programs. As a condition of receiving these grants and

federal funding, UTHSCH certifies to the granting agency that it will put in place and implement oversight procedures that will identify and rectify instances of research misconduct. Every institution that receives or applies for a research grant, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by 42 CFR Part 93, "Public Health Service Policies on Research Misconduct." (Ex. 14) In checking the "I agree" box on line 18 of the FWA, SF424 (R&R) Cover Component (Ex. 15), the Authorized Organizational Representative of the applicant organization certifies that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 93;
2. The institution has established -policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January. (Ex. 14 CFR Part 93, "Public Health Service Policies on Research Misconduct."; 42 CFR Part 50, Subpart A; 42 CFR Part 94; 42 CFR Part 50, Subpart A, and 42 CFR Part 94)

As noted above, an institution participating in federal funding for scientific research is required to "comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct

whistleblowers under 42 CFR Part 93” The protection for “whistleblowers” is found at 42 CFR §93.300. It provides:

Institutions under this part must:

- (a) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and protect them from retaliation by respondents and other institutional members.
- (b) Provide confidentiality to the extent required by §93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence.

The duty to preserve the confidentiality of complainants such as King is described in 42 CFR §93.108 as follows:

- (a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however that:
  - (1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under §93.403.
  - (2) Under §93.517 (g), HHS administrative hearings must be open to the public.
- (b) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

The oversight procedures that UTHSCH certified to the granting agencies as being in place as a condition for receiving federal grant funding is also found in the UTHSCH Handbook of Operating Procedures. (UTHSCH HOOP) Pursuant to the UTHSCH HOOP, upon receiving an

allegation of scientific misconduct, a Research Integrity Officer (RIO) is required to determine whether there is sufficient evidence to warrant a formal "inquiry". (Ex.11, App. C, Section II, A) The findings of the RIO are then reviewed by the Executive Vice President of Research, (EVPR) or his designate, who makes the final decision about whether a formal inquiry will be initiated. (Ex. 11, App. C, Section II, D) If an inquiry is not initiated by the EVPR after this initial review, no further action is taken to investigate the allegations of research misconduct and the complaint is closed. (Ex. 11, Appendix C, Section V., A) According to the UTHSCH HOOP, upon receiving an allegation of scientific misconduct, the EVPR will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry. Of course the UTHSCH HOOP also provides for the protection of "whistleblowers" or complainants who make good faith reports of scientific misconduct from retaliation or attacks on their reputation or careers. (Ex.11, App. Section II, B; see also Ex. 16, Chapter 2.17.1)

15. As a result of King's objections to Davies and others with apparent conflicts of interest, Dr. Stephen Daiger (hereinafter 'Daiger') was appointed to evaluate King's allegations. (Ex. 17) Daiger did not interview any of the witnesses identified by King. Daiger found that King's allegations did not warrant the initiation of an inquiry under UTHSCH's HOOP. Therefore, no further action was taken with regard to King's report of scientific misconduct on the part of Milewicz. King's complaint was closed without further action.

16. Soon after the decision to not initiate a formal inquiry of King's allegations, but before King was notified that a formal inquiry was not being initiated against Milewicz, Davies met with Milewicz. Within 15 minutes of the conclusion of that meeting, King was identified publically as the complainant. King learned about this breach of confidentiality from Tran VanTran-Fadulu (hereinafter Tran-Fadulu) who was a Genetic Counselor in Milewicz's lab. Tran-

Fadulu told King that a coworker in Milewicz's lab, Ralph Johnson (hereinafter 'Johnson'), knew that King had made allegations of scientific misconduct against Milewicz. King contacted Parson's immediately on July 17, 2007 and met with her on July 20, 2007 to discuss this apparent breach of King's confidentiality as the reportee against Milewicz. (Ex. 19, July 22, 2007, email, King and Parsons). King questioned why Davies was involved at all in discussing King's allegations with Milewicz after King had specifically raised the concern that Davies would reveal King's identity to Milewicz. (Ex. 19, id) King further asked if it was Daiger or Davies who made the decision to not institute an inquiry, and requested an opportunity to review Daiger's report on the matter. (Ex. 19, id) King also specifically asked if Daiger had interviewed any of the witnesses provided by King to the UTHSCH Office of Compliance. (Ex. 19, id) King knew that none of the witnesses she was still in contact with had been interviewed. In response to these questions, Parsons arranged a meeting with Arlene Staller (hereinafter 'Staller'), Vice President and Chief Legal and Compliance Officer at UTHSCH. That meeting took place on or about July 30, 2009. (Ex. 19, July 26, 2007, email, King and Parsons) In that meeting with King, Parsons and Staller would not reveal the reason that Davies discussed the allegations or findings with Milewicz. Parsons and Staller confirmed that King's allegations against Milewicz would not proceed to the level of a formal inquiry under UTHSCH HOOP. King asked what UTHSCH would or could do to protect King from retaliation from Milewicz. Parsons and Staller said that there was little the institution could do to protect her other than investigate any complaints King brought about future retaliation. King also asked if Milewicz would suffer any consequences for publicly announcing that King had instituted a complaint against her. Parsons and Staller said that there would be no consequence to Milewicz for this conduct. Parsons and Staller confirmed that none of the witnesses provided by King were interviewed by Daiger or anyone in the Office

of Compliance. Parsons and Staller stated that it was their policy to only interview witnesses that came forward on their own accord and that they never initiate contact with such witnesses. King pointed out to Parsons and Staller that it was highly unlikely that any witnesses would come forward regarding Milewicz after observing how King had been treated by the UTHSCH Office of Compliance, particularly with regard to the breach of her confidentiality and anonymity as the reportee. Parsons and Staller indicated that they would particularly like to talk to Tran-Fadulu and asked King to encourage her to come forward. King pointed out the obvious. There was no chance that any current employee of Milewicz would come forward, particularly Tran-Fadulu, for fear that their identity would be disclosed and thereby exposing them to retaliation from Milewicz. Parsons and Staller asked King what type of retaliation she anticipated from Milewicz, since King was no longer working in Milewicz's lab. King told them that she was concerned about promotion and tenure and the effect that Milewicz or other faculty members influenced by Milewicz might have on King's tenure consideration. (Ex. 20, July 23, 2007, email. King to Landry) King was about to take her clinical boards and add a clinical component to her body of work that was necessary for the consideration of her promotion and tenure. This was a very important phase of her work towards promotion and tenure and King did not want the public disclosure of her as a compliance reportee to interfere with the development of this clinical component.

17. Unfortunately, King did become a victim of retaliation. As feared, a close associate of Milewicz, Dr. Hope Northrup (hereinafter 'Northrup'), took various actions that virtually stopped King's advancement toward promotion and tenure. Northrup blocked King's ability to complete research projects in which she was the principal investigator, obstructed King's ability to apply for grant funding, and blocked all attempts by King to develop a clinical

component in her body of work. (Ex. 21, September 12, 2007, email chain, King and Northrup) Further, Milewicz had continued to make public statements revealing that King had instituted an investigation of Milewicz's lab and those disclosures were causing King to become more and more isolated within the institution. Colleagues and UTHSCH employees were avoiding contact with King for fear that it would attract the ire of either Milewicz or Northrup or both. The hostility became overwhelming for King, who decided on September 16, 2007 to submit her resignation effective November 1, 2007. (Ex. 22, King, Resignation Email) While preparing to leave the institution, King filed a formal complaint alleging that Milewicz and Northrup were retaliating against King. (Ex. 23, October 5, 2007, email chain, King and Parsons; Ex. 24, Retaliation Complaint, October 8, 2007) King alleged that Northrup's obstructive activities were a direct result of her being identified as the reportee of Milewicz's scientific misconduct. After instituting this retaliation complaint, King learned that Milewicz was now publicly announcing that King had "begun legal proceedings against Milewicz". King notified Parsons that Milewicz was again publicly disclosing King as a reportee of scientific misconduct, yet another example of how the UTHSCH Office of Compliance had breached her confidentiality and was failing to protect her as a good faith reportee of alleged scientific misconduct. (Ex. 25, email, King to Parsons, October 17, 2007) On or about October 18, 2007, Parsons notified King that at least one witness named by King in her retaliation complaint, Dr. Jack Fletcher, was refusing to discuss what he knew about the situation without authorization from both Northrup and King. (Ex. 26 email, Parsons to King, October 18, 2007) King discussed this with Dr. Fletcher who told her he would not discuss any part of what he knew with the UTHSCH Office of Compliance. On or about October 29, 2009, UTHSCH informed King that her allegations of retaliation had been investigated and found to be unsubstantiated. (Ex. 27, Memo from Arlene



Staller, October 29, 2007) This confirmed King's choice to resign. UTHSCH had breached its duty to protect her as a good faith reportee of scientific misconduct and as a result, making the prospects of being awarded promotion and tenure, slim at best.

18. On or about October 30, 2007, King was called by Dean Giuseppe Colasurdo (hereinafter, 'Colasurdo') who requested a meeting with King. King and Colasurdo met in his office. Colasurdo offered to intervene in what he saw as merely a personality conflict between Northrup and King. Colasurdo wanted to find a way for King to remain a part of the faculty at UTHSCH. Colasurdo made assurances that steps would be taken so that King would be given every opportunity to develop a clinical practice, seek grant funding, move forward on her tenure track, as well as have a position in the Division of Medical Genetics free from Northrup's interference. Colasurdo offered King a transfer to the Children's Learning Institute under the direction of Dr. Susan Landry (hereinafter 'Landry'), where King would be collaborating with Dr. Jacquilyn Hecht (hereinafter 'Hecht') and free from any interference from Northrup. King and Colasurdo briefly discussed King's formal complaint of retaliation against Northrup and Milewicz. Colasurdo confessed that he had instructed faculty and staff to not participate in any investigation of that complaint. Specifically, Colasurdo told King that he had instructed Michael Gambello and Jacqui Hecht to not participate in the retaliation investigation. On or about November 6, 2007, King had a meeting with Northrup and Dr. Fletcher regarding King's continued use of databases that were also being utilized by Northrup. Although Fletcher was supportive of continued access for King's research to the data, Northrup flatly refused to allow King any access to the data. (Ex. 28, Email, Northrup to King, November 7, 2007) Colasurdo also suggested that King discuss with Dr. Hecht the possibilities of collaboration on research projects. King met with Dr. Hecht on or about November 7, 2007 and Dr. Hecht said that she

would under no circumstances consider working with King. Hecht stated that King's retaliation claim against Northrup was a principal reason for refusing any collaboration. Even though Dr. Hecht rebuffed King and Colasurdo's suggestion of collaboration, and Northrup continued her obstructive behavior toward King, and after much reflection and weighing the loss of a 6 1/2 year career at UTHSCH, King accepted Colasurdo's offer, and transitioned to the Children's Learning Institute in an attempt to rebuild her career at UTHSCH. It was clear to King however, that the failure of UTHSCH to protect her as the reportee of scientific research misconduct and retaliatory actions against her as a result of her report would mean that she would have to start at ground zero to get her career back on track.

19. On or about November 14, 2007 King took the first step in an attempt to get her career at UTHSCH moving again. King found a new data set, independent of Northrup's data set, that she could access to further her research on Spina Bifida. King requested that she be allowed to utilize grant money previously awarded to King to fund her analysis of this data. This request was submitted to Hecht in her capacity as Vice Chair of Research. King needed Hecht's permission to transfer these funds, which were originally awarded for research dependent upon Northrup's samples, to the new samples. Dr. Hecht refused this request. Dr. Hecht supported her decision by noting that Northrup was doing research on the issue of Spina Bifida and to allow King to do similar research on that subject would put King in competition with Northrup. Hecht further noted that originally King and Northrup were collaborating on Spina Bifida research, but since that relationship had been terminated, King could not continue on her own research concerning Spina Bifida using existing data at UTHSCH. (Ex. 29, Email chain, Hecht-King, November 19, 2007) King now realized that UTHSCH had decided that she would not be allowed to continue her Spina Bifida research, an area of research she had focused on since 2005.

20. In February 2008, King was sent a job posting for a position that King had been seeking for over a year at the UTHSCH Medical Genetics Division. Ironically, the job posting identified King as a person who was participating in the clinical rotations at the Division of Medical Genetics, even though every attempt King had made to be placed on the clinical schedule had been refused by Northrup. The job posting confirmed that UTHSCH needed someone with King's skill set and background in the clinical rotation. However, instead of accepting King's repeated requests to be placed on the clinical schedule, the institution was seeking to fill the position with someone else. (Ex. 31, Job Posting for Clinical Geneticist, February 20, 2008)

21. Since 2004, King had been consistently asked to participate as a small group leader in the medical genetics course lecture series, an annual event presented by the Medical Genetics Division. In 2007, King had been awarded a didactic lecture for the series on population genetics, which was quite an honor. On or about May 29, 2008, King contacted Dr. Hecht, who was the Course Coordinator for 2008, about preparation for the medical genetics course lectures for the upcoming year. Hecht responded to King's inquiry by saying that since King was no longer in "the division" as a result of her transfer away from Northrup, that she would not be eligible to conduct course lectures in 2008. King questioned this decision and asked Hecht to reconsider since presenting course work was an important component of King's tenure package. Without these lectures, King would be lacking in this area when she was considered for promotion and tenure. Hecht refused to reconsider this request and King was excluded as an instructor in this course work for the first time since 2004. (Ex. 32 May 29, 2008, email, King to Hecht) There was no reason to exclude King from participating in this function. Hecht claimed that King could not participate because she was no longer part of the "division" since her transfer

away from Northrup's group. The rule cited by Hecht had never been enforced prior to this time. This was yet another example of how King was repeatedly blocked in her attempt to attain tenure at UTHSCH.

22. The above referenced obstacles to performing research, developing a clinical practice and teaching/lecturing forced King into a no win situation concerning her tenure track. UTHSCH has a policy of faculty members on tenure track to either achieve tenure within 9 years or be denied tenure. In 2008, King was toward the end of her seventh (7<sup>th</sup>) year on the UTHSCH tenure track. With all the obstacles placed in her path by Northrup, Milewicz, Hecht and other faculty members associated with this closely associated trio, it was apparent that King would not be able to timely complete work on her tenure "package" that would merit the award of tenure in the year she had left to complete her tenure track. Therefore, King was forced to remove herself from the tenure track at the time of her 2008 faculty review on or about May 21, 2008. (Ex. 33, Email, King to Landry and Swank, May 21, 2008)

23. Tran-Fadulu, who had worked as a genetic counselor for UTHSCH in Milewicz's Lab, resigned in 2009 and requested an exit interview for the purpose of disclosing information about Milewicz's research misconduct. Tran-Fadulu disclosed that information to the Human Resources Department of UTHSCH, and then submitted a formal written complaint about her personal observations of Milewicz's scientific misconduct to the Office of Compliance at UTHSCH. In February of 2009 Tran-Fadulu submitted a memorandum of her observations of Milewicz's misconduct including:

- misappropriation and mismanagement of federal funds and materials purchased with federal funds;
- failure to follow mandated protocols related to obtaining informed consent from human subjects participating in research;

- allowing non licensed physicians with only a medical degree and no residency training to perform clinic visits and make genetic diagnosis of study participants that were then billed as physician visits;
- mismanagement of lab blood and tissue samples; and
- manipulation and falsification of research data through harassment and intimidation by Milewicz of faculty, graduate students and lab personnel.

24. Specifically, Tran-Fadulu witnessed Milewicz instruct and require a fellow genetic counselor, who's salary was 100% funded by one NIH grant, to spend substantial amounts of time working on another NIH grant. This is a clear violation of NIH regulations and the conditions of the grants involved. Tran-Fadulu specifically named three (3) research assistants, Dipal Divecha, Asha Intwala, and Sean Yee, who were paid largely through a federal grant to the Core Lab of UTHSCH, but were instructed by Milewicz to work on her primary grant projects rather than the work funded by the federal grants that paid their salary. Tran-Fadulu revealed to UTHSCH officials that a digital camera purchased with federal grant money was primarily used by Milewicz's family. The digital camera was purchased so that Milewicz's staff could document research and clinical patient's physical abnormalities that may be related to genetic makeup. However, the camera was unavailable for staff use because Milewicz allowed her family to use it for extended periods of time. Tran-Fadulu reported to UTHSCH compliance officials that Milewicz was commingling funds from various NIH grants, another violation of NIH grant regulations, and provided UTHSCH with names of specific current employees who were charged with monitoring these funds who would verify these violations. Tran-Fadulu also reported significant compliance issues regarding the collection of samples and obtaining informed consent from human research subjects. Tran-Fadulu reported that international customs

regulations were routinely ignored at the instruction of Milewicz when tissue samples were obtained from abroad. Tran-Fadulu reported that she knew tissue and blood samples were often accepted from human subjects without obtaining any form of informed consent at the direction of Milewicz, a very serious violation of NIH protocols and the Office of Human Research Protections of the United States Department of Health and Human Services. One method Tran-Fadulu observed Milewicz use to obtain non consented tissue samples, was to accept them from physicians that Milewicz knew personally or professionally. Milewicz accepted these tissue samples from surgeons without requiring that those providers outside the UTHSCH system submit to the process of obtaining these samples to their Institutional Review Board for approval. This is a required step in obtaining effective and legal consent from the donor or the donor's family when two institutions collaborate in research using human subjects. Milewicz would further violate these rules by having the outside physicians sign the consent forms as if they were UTHSCH study personnel, thus illegally circumventing proper consenting regulations. Tran-Fadulu provided the compliance office of UTHSCH with specific examples of non-consented tissue samples that were run for DNA analysis without proper and legal consent being obtained from the donors or the donor's family. She also confirmed that the testing of the non-consented tissue samples was done at the direct instruction of Milewicz who knew there was no valid consent form signed by the donor or donor's family. Tran-Fadulu also reported that Milewicz went as far as instructing genetic counselors in her lab to sign their own names to consent forms without ever having had any direct contact with the subject donor. Consent without ever meeting with or talking to the donor is an invalid method of consent for human research and use of that sample in research funded by federal grants is a violation of the terms of those grants. Tran-Fadulu also reported that Milewicz would knowingly obtain consent from research patients on

one study and then if they did not fit the criterion for the study to which they consented, Milewicz would shift the samples to another study and run tests on those samples for which consent had not been obtained. The shifting of samples and human research subjects from one study to another without proper informed consent is another serious violation of federal grant conditions and protocols as well as a violation of the standards for human research promulgated by the Office of Human Research Protections of the United States Department of Health and Human Services. Tran-Fadulu also reported that Milewicz would inflate her enrollment numbers of study participants by instructing the genetic counselors working under her to enroll participants who did not fit any of the study criterions. Tran-Fadulu further reported that Dr. Milewicz allowed non licensed physicians to perform genetic diagnosis in her clinic without any formal genetics training. Tran-Fadulu submitted the names of two men who performed these clinic visits, Charles Minn M.D. and Scott Bourgois, M.D. Tran-Fadulu also reported that data on a published article by Milewicz had been found to be non-reproducible, leading to the elimination of at least one family's data set. The elimination of this one family from Milewicz's data made her conclusions erroneous and misleading. Tran-Fadulu pointed out to the UTHSCH that under these circumstances, the article should have been retracted. Tran-Fadulu identified the article in question: "Familial Thoracic Aortic Aneurysms and Dissections: [Genetic Heterogeneity with major locus mapping to 5q13-14"; Guo D. et al, Circulation, 2001 May 22; 103 (20): 2461-8.] Further, Tran-Fadulu reported that the person in Milewicz's lab who discovered the flaw in the data supporting this article, Dr. Quy Phung, was subsequently disciplined by Milewicz. The research supporting this published article was paid for by NIH Grant RO1 HL62594-01A2, Genetic Basis of Aortic Aneurysms/Dissections, Doris Duke, Distinguished Clinical Scientist Award, Genetic Basis of Aortic Aneurysms and Dissections.

Tran-Fadulu also reported an incident of mismatching and or mislabeling of samples from the participants in this research. Tran-Fadulu provided UTHSCH with an example of this mismatching or mislabeling of samples relating to a specific family, denoted family TAA059, who were part of the work federally funded by NIH Grant RO1 HL62594-01A2. Tran-Fadulu provided UTHSCH with information regarding retaliation against faculty and staff members working under Milewicz that was reminiscent of the report King made in 2007. Tran-Fadulu reported that two (2) researchers, Hariyadarshi Pannu, Ph.D. and Dipal Divcha, who had contributed significantly to manuscripts subsequently published by Milewicz, had their names removed from the published version in retaliation against those researchers for having left her lab to go to work at other positions at UTHSCH. Tran-Fadulu further supported King's 2007 reports by identifying fabrication or falsification of lab data as a result of Milewicz's practice of humiliating and intimidating faculty and staff members who presented data that was adverse to or not supportive of Milewicz's hypothesis. Tran-Fadulu observed and reported that after suffering Milewicz's wrath, intimidated staff would suddenly report the same data as positive and supportive of Milewicz's hypothesis.

25. As a result of Tran-Fadulu's report to UTHSCH upon her exit interview both the UTHSCH Office of Compliance and the Institutional Review Board (IRB) of UTHSCH were notified of her allegations. The UTHSCH IRB has the power to order an immediate audit for cause of a researcher's work based on allegations or information they find to have some merit. (UTHSCH Handbook of Operating Procedures (Ex. 11, HOOP § 23.04 Appendix C) However, the IRB's power to investigate any misconduct through an audit for cause is limited until the UTHSCH Executive Vice President of Research (EVPR) reviews the evidence and opens an "inquiry" into the allegations. (Ex. 11, HOOP § 23.04 Appendix C) For example, prior to the



inquiry stage, the IRB could only audit the specific grant or conduct related to the complaint or allegation and was powerless to seize control of Milewicz's files pending resolution of the allegations. However, if an "inquiry" is opened by the EVPR, the first step of that inquiry, according to UTHSCH policy, would be to take control of Milewicz's files. (Ex. 11, UTHSCH HOOP 2. (B) Sequestration of Research Records) Upon receiving the information provided by Tran-Fadulu, the UTHSC IRB ordered a "for cause" audit of Milewicz's work and the documentation of informed consent for one of Milewicz's NIH grants. This audit revealed that a very high percentage of the required research participant consent documentation for Milewicz's research subjects could not be located. The IRB expanded their audit further back in time and found an even greater percentage of consent documentation was lacking. Suddenly, and without explanation, Milewicz produced a large number of the consent forms that initially could not be located. In spite of this last minute production of documentation by Milewicz, there were still substantial discrepancies regarding her consent documentation, as alleged by Tran-Fadulu. The IRB concluded that this evidence was an indication of serious non-compliance. The IRB then questioned whether or not Milewicz' noncompliance was "ongoing." The IRB suspended Milewicz' research protocol involved in the audit of consent documentation based on the information gathered in the for cause audit. However, unless the EVPR reviewed their findings and called for a "formal inquiry" under UTHSCH's HOOP, the IRB could not dig any further into the scope of Milewicz's consent non-compliance.

27. The allegations of Tran-Fandulu were also forwarded by the UTHSCH Office of Compliance to the EVPR, Dr. Peter Davies (Davies). The UTHSCH policies, as found in the UTHSCH Handbook of Operating Procedures (HOOP), calls for the EVPR, upon receiving allegations of scientific misconduct to *immediately* assess the allegation to determine whether

there is: 1) sufficient evidence to warrant a formal “inquiry”; 2) Public Health Support (PHS) or PHS applications for funding are involved; and 3) an allegation falls under the PHS definition of scientific misconduct. (Ex. 11, UTHSCH HOOP § 23.04, IV. (E) Preliminary Assessment of Allegations) Once there is a prima facie showing that these three (3) elements have been met, UTHSCH policies dictate that an inquiry shall start immediately. (Ex. 11, UTHSCH HOOP § 23.04, V. (A) Initiation and Purpose of the Inquiry) Once an inquiry is initiated by the EVPR and the relevant research records are sequestered, the EVPR must appoint a committee to conduct the inquiry within ten (10) days. (Ex. 11, UTHSCH HOOP § 23.04, V. (C), Appointment of the Inquiry Committee) The committee is charged with marshalling the evidence, talking to witnesses and performing audits, for the purpose of determining whether there is sufficient evidence of possible scientific misconduct to warrant a formal investigation. (Ex. 11, UTHSCH HOOP § 23.04, V. (A), Initiation and Purpose of the Inquiry) The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the Respondent, complainant, and key witnesses to determine whether there is sufficient evidence of *possible* scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. (Ex. 11, UTHSCH HOOP § 23.04, V- A. Initiation and Purpose of the Inquiry) Unfortunately, after being presented with the allegations of Tran-Fadulu, Davies did not call for an inquiry and the IRB was unable to expand its audit to determine if what they had found in their first two (2) audits was an indication of more wide spread scientific misconduct on the part of Milewicz.

28. On or about February 18, 2009, King became aware that Tran Fadulu had made allegations of scientific misconduct against Milewicz that were very similar to King’s allegations in 2007. Tran Fadulu contacted King and asked King to contact the UTHSCH Office of

Compliance that was investigating Tran Fadulu's allegations against Milewicz. Tran-Fadulu specifically wanted King to provide further information to the UTHSCH compliance office regarding financial misconduct and misuse of federal grant funds. King did not immediately contact the UTHSCH IRB, of which she was a member. King was reluctant to get involved, still reeling from the retaliation and mistreatment she received from UTHSCH after her report of scientific misconduct in 2007.

29. On or about April 9, 2009, Tran- Fadulu again contacted King and asked her to contact the UTHSCH IRB and provide supporting information regarding Tran-Fadulu's allegations. On April 9, 2009, King contacted Parsons for advice about whether or not to participate in the Tran-Fadulu investigation (Ex. 34, Email King to Parsons, April 9, 2009). King told Parsons that Tran-Fadulu had contacted King on several occasions regarding Tran-Fadulu's allegations. King told Parsons that Tran- Fadulu had asked King to come forward and reveal her knowledge of misuse of federal grant money in Milewicz's lab as well as research misconduct. On or about April 10, 2009, Parsons requested that King confer with her regarding these matters. King and Parsons spoke by phone on or about April 14, 2009. Parsons told King that her participation in the investigation was not required and if the IRB wanted to interview King, they would initiate contact with King. This seemed odd since King had been told that the investigative procedure of UTHSCH was to only talk to witnesses who contacted them. King asked Parsons specifically whether or not King's 2007 information regarding Milewicz' misconduct had been provided to any investigative committee. Parsons responded that all the information provided by King in 2007 regarding Milewicz's lab had been given to the committees under the heading of "credible but not proven".

30. In May of 2009, King was a member of IRB committee #2 at UTHSCH. There are three IRB committees. As a matter of pure chance, King attended a meeting of IRB committee #1 on or about May 1, 2009 after a general request went out to all IRB members to attend a specific committee meeting that was having trouble making a quorum. (Ex. 35, Email to King, April 20, 2009) King was surprised to find herself in an IRB committee meeting discussing Tran-Fadulu's allegations against Milewicz. During that meeting, King reviewed the conflict of interest definitions of the IRB and concluded that, while she did not have a good relationship with Milewicz, she did not meet the criterion for recusing herself from the discussion of the Milewicz matter because of a conflict of interest. King abstained from voting on any motions related to the Tran-Fadulu initiated investigation of Milewicz and did not participate in any of the discussions of that investigation while in attendance at this meeting of UTHSCH IRB Committee #1. On or about May 14, 2008, King was sent a general call for attendance for an *ad hoc* subcommittee meeting of IRB Committee #1. (Ex. 37, Email to King, May 14, 2009) King had been assigned to a separate subcommittee of UTHSCH IRB Committee #1 to investigate another protocol, unrelated to the Tran-Fadulu allegations against Milewicz. King mistakenly believed that the *ad hoc* meeting was called to discuss the unrelated protocol. During that second meeting, on or about May 20, 2008, the *ad hoc* subcommittee reviewed findings from the "for cause" audit of Milewicz's research. UTHSCH Committee #1 had called for an audit of Milewicz's compliance with human research subject consent procedures mandated by the DHHS Regulations. That audit had been completed and had found a high incidence of noncompliance with the mandated human research subject consent procedures. The level of noncompliance was characterized as "serious". King witnessed the deliberations of the IRB committee concerning these findings. There was frustration voiced by most committee members with the organizational

constraints placed on the IRB by UTHSCH policies, that limited the scope of their fact finding with regard to Milewicz. The general feeling of the IRB committee was that further investigation was needed to determine whether or not the serious noncompliance found in their audit was ongoing. If in fact further investigation of the noncompliant practices discovered in Milewicz's lab revealed that the noncompliance was continuing, this would require that the IRB's finding of "serious noncompliance" would be upgraded to the highest level of misconduct, known as "continuing non-compliance". A finding of "continuing noncompliance" would require notification of the United States Office for Human Research Protections (OHRP), (formerly the Office for Protection of Research Risks). Such a notification to the United States OHRP would risk adverse action from that agency including the suspension of further funding for Milewicz and/or her debarment from receiving further federal funding on a permanent basis. There was also the risk that the disclosure of such serious noncompliance could jeopardize all federal funding for UTHSCH or subject the institution to greater scrutiny from the federal government regarding federal funding of research. However, the IRB Committee's power to do further investigation was constrained by the UTHSCH HOOP, and the only way the institution was going to discover the full scope of Milewicz's noncompliance would be if a formal inquiry and/or investigation was called by the UTHSCH Office of Compliance. Even though the allegations by Tran-Fadulu had been before the UTHSCH Office of Compliance over four (4) months and the UTHSCH HOOP required the EVPR, Davies, to make a determination about whether to call an inquiry "immediately", no inquiry had been called by Davies and therefore, the UTHSCH IRB's hands were tied and they could not expand their fact finding regarding the scope of Milewicz' noncompliance.

31. As a member of the IRB, King became aware of the details in the complaint filed by Tran-Fadulu. The allegation that Milewicz's data supporting her published works could not be duplicated was consistent with King's experience in 2007 when she worked in Milewicz's lab. King began a review of the published work authored by Milewicz. King found that Milewicz had made errors in the presentation and interpretation of data that could be demonstrated on the face of the published works. King has further found that the "errors" were biased to support the hypothesis of Milewicz. In other words, if presented and interpreted properly, the statistical analysis of Milewicz's claimed relationship of a particular genotype to the likelihood of Aortic Dissections would have revealed the inconsistencies in her data. However, by interpreting the data incorrectly, the relationship reported was statistically significant. King's review revealed that the seminal work upon which much of Milewicz's later grant applications were based was fundamentally flawed and misleading in its conclusions about the statistical significance of the genotype Milewicz was claiming to be associated with Aortic Dissections. (Ex. 59, King's analysis of Milewicz publication: Genetic Heterogeneity with major locus mapping to 5q13-14. Guo D. et al. Circulation. 2001 May 22; 103 (20): 2461-8). Since that time, King has performed additional reviews of several other articles published by Milewicz. Those reviews have revealed similar and ongoing data integrity and interpretation issues calling Milewicz' research into serious question. (see Ex. 59, King\_Analysis of Selected Milewicz Publications)

32. The misleading conclusions King discovered in Milewicz' published work, raised issues about the integrity of all federal grant applications by Milewicz in the area of attempting to identify a genotype that is related to the incidence of Aortic Dissections. The procurement of federal grant money is competitive to say the least. There is only so much money to go around and the granting agencies must discern which research proposals are most likely to lead to

fruitful discoveries. The erroneous reporting of a statistically significant relationship between a hypothesized genotype and the likelihood of Aortic Dissection made Milewicz's next grant request for more research money much more attractive to the granting agencies. Had Milewicz accurately reported her data as showing a weak statistical relationship between her hypothesized genotype and aortic dissections, all subsequent grant applications would have been much less attractive to granting agencies reviewing those grant applications. On the back of her erroneous conclusions, Milewicz has amassed awards of federal grants for further research in this area in excess of \$21,000,000.00 (Twenty One Million Dollars).

33. King was shocked by the UTHSCH IRB's audit findings of Milewicz's noncompliant consent practices and her findings of Milewicz's inaccurate published works. After the May 20, 2009 meeting, King disclosed to the Chair of IRB Panel #1, Dr. Richard Kirkedee (hereinafter 'Kirkedee'), that she had material information related to the current investigation into Milewicz's laboratory practices. King met with Kirkedee and Anne Dogherty (hereinafter 'Dogherty'), Executive Chair of the IRB. King disclosed the information she had included in her complaint against Milewicz in 2007 and how it was relevant to the present investigation. King presented a memorandum to Kirkedee and Dogherty outlining her knowledge of Milewicz's scientific misconduct. (Ex. 37, May 27, 2009, email chain, King, Kirkedee, with supporting data) Kirkedee and Dogherty were unaware of the existence of King's 2007 complaint and its overlap with the 2009 complaint lodged by Tran-Fadulu. In addition, King informed Kirkedee and Dogherty that Milewicz had been seen with staff members sifting through research documents with a trash can and paper shredder nearby. King further disclosed that a member of the special IRB subcommittee that conducted the audit of Milewicz, Dr. Maximillian Buja (hereinafter 'Buja'), was partially funded by the Milewicz grant that was being audited as well as

being an active and current collaborator with Milewicz. King was told by Kirkedee and Dogherty that Milewicz had been highly antagonistic and confrontational during the audit, going as far as frisking the auditor every day at the conclusion of the auditor's work. Dogherty relayed to King that Milewicz, in an attempt to intimidate the investigative subcommittee, threatened Buja with a sexual harassment suit. After this initial meeting with Kirkedee and Dougherty, King forwarded some of the details of her analysis of Milewicz's published works showing errors in the data. (Ex. 38, Email from King to Kirkedee and Dogherty and attached spreadsheet, June 1, 2009) Further, King made contact with Tran-Fadulu and Dawn Simmons, a former employee in Milewicz's lab. King facilitated a meeting between Kirkedee, Dogherty and Tran-Fadulu. (Ex. 37, King to Kirkedee re Tran interview, May 26, 2009)

34. On or about June 11, 2009, Dogherty contacted King and requested that she contact Parsons in the UTHSCH Office of Compliance. King responded to this request on or about June 11, 2009. (Ex. 39, June 11, 2009, email King to Parsons re: meeting) On or about June 12, 2009, King informed Parsons, Kirkedee and Doherty that King had learned that Milewicz was retaliating against a Genetic Counselor, Clair Knoll, who was working in Milewicz's lab. (Ex. 40, Email King to Parsons, June 12, 2009) King had learned that Milewicz suspected Knoll of being the reportee of misconduct that had led to the IRB investigation of Milewicz. The source of King's report was Tran Fadulu. King reported to Parsons, Kirkedee and Doherty that Milewicz was using some of the same retaliatory tactics against Knoll that Milewicz used against King in 2007. Neither Parsons, Kirkedee nor Doherty ever responded to this report of retaliation against Knoll or contacted King for further information. King then met with Parsons in a face-to-face meeting on or about June 15, 2009. The first question Parson's asked was, "Why did you say that Peter Davies "outed you" concerning King's 2007 complaint. King



again provided Parsons with the basis of her conclusion that Davies disclosed her identity to Milewicz as the reportee of scientific misconduct by Milewicz in 2007. Parsons discounted King's basis and stated that based on the "file", there was no way Davies knew that King was the reportee. King provided to Parsons much of the same information she had provided to Kirkedee and Dogherty, in some cases providing more detail. (Ex. 41) King and Parsons reviewed a spreadsheet prepared by King that had been previously provided to Kirkedee, detailing King's findings regarding errors in the underlying data in some of Milewicz's published works. King discussed with Parsons the issue of document destruction in Milewicz's lab after the IRB audit was announced but had not yet begun. King believed it was important that the Office of Compliance be aware of the potential for document destruction. King believed that such evidence should be immediately forwarded to the EVPR. Davies, for the purposes of his initial assessment of the allegations and his decision of whether or not to initiate a formal inquiry. King knew that any further delay in starting a formal inquiry, now over five (5) months since Tran-Fadulu's allegations, would create an opportunity for Milewicz to alter and/or destroy incriminating documents. King became aware of Milewicz's alleged document tampering based on the witness accounts directly from Milewicz's staff. King offered to provide names of witnesses to the possible document tampering and destruction to both the IRB and the Office of Compliance in hopes that this would create a sense of urgency and cause the EVPR. Davies, to initiate an inquiry sooner rather than later so that any remaining documents could be immediately sequestered and protected according to DHHS Guidelines, Federal Regulations and the UTHSCH HOOP. King asked Parsons about how the investigation was proceeding. Parsons revealed that there were five (5) separate committees investigating various components of the allegations and that Parsons and the UTHSCH Office of Compliance was coordinating the investigation. King

questioned Parsons about whether the committees were talking to each other about their respective findings and questions concerning Milewicz. King was mindful of this issue because of her experience in UTHSCH IRB Committee #1 wherein it was specifically stated that there could be no discussion in one committee about what was going on in another.

35. Prior to June 11, 2009, soon after King disclosed to Doherty and Kirkedee the facts of her complaint in 2007, Doherty and Kirkedee took the details of King's 2007 and new 2009 allegations to the IRB Subcommittee that was created to investigate Milewicz's research violations. Doherty and Kirkedee also disclosed to the IRB subcommittee the allegations concerning the disclosure of King's identity immediately after a meeting between Milewicz and Davies. In spite of King's disclosure that Buja had a potential conflict of interest as a member of the IRB subcommittee, Buja continued to serve on the subcommittee. After hearing the details of King's 2007 allegations and the updated information she provide in 2009, the IRB subcommittee invited the Executive Vice President of Research, Davies, to a committee meeting to inform him that there were additional allegations of misconduct beyond consent protocol violations and that there had been a complaint lodged by King regarding scientific misconduct in 2007. Doherty and Kirkedee informed King that the IRB subcommittee had summoned Davies to let him know that the scope of Milewicz's misconduct was potentially greater than just the consent violations they were authorized to investigate.

36. King continued her regular attendance of IRB Committee Panel #2, as a slated member throughout 2009. New and different allegations of misconduct were brought to IRB Committee Panel # 2 regarding noncompliance by Milewicz in the summer of 2009. These allegations centered on some lost samples in Milewicz's East Texas Bleeding Disorder Study. (Ex. 40a, IRB Committee Panel #2, Memorandum of Record from Jay Johnson; "Bleeding

Disorders, East Texas Type", Update 9/30/09, last page) The allegations being examined by panel #2, on their face, were relatively minor in comparison to what was being investigated by IRB Committee Panel #1. However, Committee Panel #2 members were not told that King had raised questions about the accuracy of the data and analysis by Milewicz in this same study. Further, Panel # 2 was not told during their deliberations that Milewicz's research had been suspended for noncompliance by IRB Committee Panel #1 regarding another Milewicz study. Knowing what she knew, King was very uncomfortable with sitting on Panel #2 and not disclosing these facts. King asked Dougherty for advice about how to handle the discrepancy about what she knew and what she was allowed to disclose to Panel #2. Dougherty advised her to just "abstain" from the deliberations and any votes. (Ex. 40b, email, Doherty to King, June 30, 2009) The fact that these two committees were operating in a vacuum and completely unaware of what the other was looking at with regard to Milewicz was not an accident.

37. In approximately 2003, Davies changed the structure of the IRB committee. Prior to 2003, there was only one IRB committee overseeing all research compliance issues. Davies created a new IRB committee and later a third committee. This organizational structure resulted in barriers between the committees so that each one operated completely independently. The decision of what issues would be handled by which of the now three (3) committees was randomly assigned. In essence, each committee had jurisdiction only over protocols that they were asked to review by the UTHSCH Office of Compliance. Policies regarding programmatic queries and jurisdiction were conflicting in the guidelines. However, in all training materials and in structure, all research misconduct and non-compliance were ultimately controlled by the Office of Compliance and Davies. Some of the members of the IRB objected to this change. They felt it would compromise the ability of the IRB to perform its oversight function because of

compartmentalization and administrative constraints that prevented one committee from knowing what the other committees were examining. IRB Committee Panel #2 viewed the small part of the noncompliance issues regarding Milewicz parceled out to them as a minor infraction, not worthy of substantial scrutiny.

38. During King's June 2009 meetings with Parsons, King was told of the existence of five (5) committees that were investigating Milewicz. King inquired if the committees were coordinating their efforts. King cited the example of the potential findings of an employment investigation concerning harassment and intimidation that may be of some relevance to the research integrity committee. King told Parsons that it would be difficult "to connect the dots" as to why technicians and students would falsify data if the committee investigating the data integrity issue was not aware of the extraordinary levels of harassment and intimidation in Milewicz's laboratory. Parsons responded that there was no reason for the committees to share their findings. King realized that the Office of Compliance was parsing out the various issues being raised about Milewicz to different committees so that the whole of the misconduct of Milewicz could not be understood by any one committee.

39. On or about June 26, 2009, Parsons sent a memo via email to King asking for more information regarding King's allegations against Milewicz. (Ex. 43, Email Parsons to King, June 26, 2009) King responded on or about June 26, 2009 with the information requested, to the extent she could provide the answers to Parson's requests, including names of persons who could confirm the occurrence of specific instances of misconduct in Milewicz's lab. (Ex. 44, Email King to Parsons, June 26, 2009) Parsons made a second request for further information to King on or about June 30, 2009 concerning King's analysis of two (2) of Milewicz's published articles. (Ex. 45, Email Parsons to King, June 30, 2009) King promptly responded to this request

to the extent she was able to provide the information, including again the name of the doctoral student who was unable to replicate Milewicz's results that formed the basis of one of Milewicz's published articles. (Ex. 45, Email King to Parsons, June 30, 2009) On or about July 6, 2009, Parsons inquired about the identities of exiting lab personnel that had damaged and/or destroyed lab data in response to the hostile work environment created by Milewicz. (Ex. 46, email Parsons to King, July 6, 2009) King had been reluctant to name the former employees for fear of legal consequences to those persons. Parson's insisted that the investigation into this aspect was dependent upon the disclosure of the names of the offending former employees. King provided the names of the former employees and the specifics of what they did to the lab data on or about June 26, 2009. (Ex. 46, email King to Parsons, July 6, 2009) Parsons again requested more information from King on or about July 16, 2009. (Ex. 47, email Parsons to King, July 16, 2009) King again responded promptly providing the name of the graduate student who provided Milewicz's data, Sumera Hasham, as well as an explanation of how King became aware that Hasham and Milewicz's data was incorrect. (Ex. 47, email King to Parsons, July 16, 2009)

40. After the IRB discovered in the audit of one of Milewicz's protocols, a serious lack of compliance in obtaining proper consent from human research subjects, the IRB immediately suspended that protocol. The suspension of Milewicz's protocol prohibited Milewicz from continuing to recruit human subjects for study under that protocol pursuant to UTHSC HOOP and DHHS regulations. (Ex. 11, 12 and 14) King suspected, based on accounts from insiders in Milewicz's lab, that Milewicz was still recruiting human subjects for her suspended research protocol. On or about July 8, 2009, King contacted Milewicz's lab anonymously, posing as a potential participant in Milewicz's suspended research protocol. (Ex. 48, email from King posing as Clair Wilcox) Milewicz personally responded to King's

anonymous inquiry, never indicating that the research was suspended and referred her to one of Milewicz's Genetic Counselors, Ellen R. Regalado. (hereinafter 'Regalado') Regalado actively recruited King's pseudonym participant for the study, including the collection of personal health information, providing counseling advice that included medical treatments, and telling King that it was possible to obtain results from the Milewicz laboratory that were not available elsewhere. (Ex. 49, email chain, July 17, 2009) Regalado told King that the study was under review and they were not enrolling at that time. Regalado told King that King's pseudonym participant would "definitely" be contacted when the study was enrolling again. King reported this violation to the Doherty who sits on all three IRB committees on or about July 28, 2009. (Ex. 50, King to Doherty email, July 28, 2009) Doherty asked King if King had evidence regarding this transaction and King informed Doherty that there was an audio recording of the conversation with Regalado as well as emails documenting the illegal recruiting by Milewicz. Neither the IRB nor Doherty followed up on King's report of illegal recruiting by Milewicz nor did either request a copy of the audio tape or emails.

41. On or about August 11, 2009, King was informed that the UTHSCH Office of Compliance had reviewed King's allegations regarding Milewicz and it had concluded that, "there is not sufficient evidence or justification to proceed with a research misconduct inquiry" and that "this compliance report is closed with no further action required." (Ex. 51, letter from Parsons, August 11, 2009) This decision had been made through a collaboration between Dr. Roberta Ness (Ness) and Dr. Stephen Daiger (Daiger). Interestingly, Daiger had been the scientific reviewer that had been dismissive of King's 2007 allegations against Milewicz. King immediately sent a request to the Office of Compliance requesting the following documents and information concerning the UTHSCH Office of Compliance review of King's 2009 allegations:

1) the statements of facts of the allegations; 2) the methodology used to evaluate the allegations; 3) the specific allegations that were evaluated by Ness and Daiger and 4) who was interviewed by Ness and Daiger prior to their determination. (Ex. 52, email King to Parsons, August 11, 2009) This request was treated as an open records request pursuant to the Texas Public Information Act by the Office of General Counsel to UTHSCH. (Ex. 52, FOI letter, August 18, 2009) The Office of General Counsel objected to providing this information to King based primarily upon the "peer review" exception found in the Texas Health and Safety Code. (Ex. 52, UTHSCH brief to Texas Attorney General) The Attorney General of Texas upheld UTHSCH's objection and the information was not provided to King. On or about September 4, 2009, King inquired of Parsons whether or not Milewicz had been notified that the complaint had been closed. (Ex. 53, email King to Parsons, September 4, 2009) Parson's did not reply to this request.

42. Since September of 2009, King has had no further contact with the Office of Compliance regarding either her complaint or the complaint lodged by Tran-Fadulu. However, King discovered that the UTHSCH failed to report King's 2007 complaint to the Department of Health and Human Services, Office of Research Integrity as required by DHHS regulations and the Federal Wide Assurance (FWA) signed by the UTHSCH. In its June 2008 Annual Report, the DHHS Office of Research Integrity published its annual report which documents all reports of allegations, inquiries or investigations into possible research misconduct filed by any institution that wants to maintain its FWA. Any institution that accepts Public Health Service (PHS) funding must sign and maintain a current FWA that among other things requires that the institution vigilantly perform its oversight function, protect whistleblowers and police research misconduct within the institution. This includes an annual report of all allegations of research misconduct that are received by an institution each year. According to the June 2008 Annual

Report of the DHHS Office of Research Compliance, UTHSCH did not report King's 2007 allegation of research misconduct on a form 6349, Annual Report on Possible Research Misconduct to the DHHS.

43. On or about November 4, 2009, King requested a meeting with Susan Landry about getting her career back on tenure track, as well as, pressures on King to perform non-academic duties as opposed to academic activities. At that time, Landry informed King that there would be no clinical opportunity for King because Northrup continued to refuse to allow King access to any clinical rotations. Landry informed King that her only "secure choice" would be to resign her faculty position, abandon her hopes for tenure and take a new job as a non-faculty project manager. Landry explained that taking the non-faculty position was the most "secure choice" because if King remained on the faculty, her research funding was running out, King did not have any research funding that was pending because Northrup had refused access to data that King had relied upon for future research and departmental funding of her faculty position was always a risky proposition in this day and age of cost cutting. The non-faculty position offered to King was much more secure in terms of funding for the compensation package. The offer of this non faculty position was confirmed via email from John Gasko who was to be King's new Supervisor. (Ex. 53a email chain. King, Gasko, November 10, 2009) The obliteration of King's career and aspirations to become a tenured faculty member at UTHSCH was now complete, carried out by Milewicz and her colleague Northrup and sanctioned by UTHSCH in breach of their statutory and regulatory duty to protect whistleblowers who bring good faith allegations of scientific misconduct. The UTHSCH promised to protect whistleblowers such as King in return for the right to seek and receive federal grant funds for research. King is a prime example of UTHSCH's abject failure to keep that promise.



44. Dr. King began working as a staff Statistician in the Children's Learning Institute under the direction of Paul Swank. King's principal function was preparing legislative reports and research for the State Center for Early Childhood Development. (SCEDC) King also performed a small supportive role in a clinical trial studying the effects of Erythropoietin. King raised issues about inadequate resources to perform her function of preparing legislative reports to the State Center for Early Childhood Development. King was, according to her job description, limited to spending half ( $\frac{1}{2}$ ) of her time on the completion of these reports and also complete her responsibilities regarding the clinical trial while still working on her own research and grant proposals. At times Dr. King was being forced to work 60 to 70 hours a week attempting to complete her job responsibilities on both legislative reports and the clinical trials leaving little or no time to further her research and grant proposals which were essential to her hope of getting back on tenure track. King pointed out that UTHSCH was paying approximately 40% of her salary to work on research and grants but there was not enough time in the day to complete everything she was required to do according to her job description. Essentially, UTHSCH had saddled her with so much work to do regarding the State Center for Early Childhood Development, she was unable to do enough research and grant proposals to get back on the tenure track. King again raised the issue of being scheduled for clinical time that she had been promised so many times before but never allowed to perform. Participating in a clinical setting is another essential element to King's effort to regain her tenure track status.

45. King pressed these issues with Paul Swank, her supervisor, and John Gasko, the Director of the State Center for Early Childhood Development. Swank and Gasko listened, but offered no solutions. King took these problems further up the chain of command to Swank's supervisor, Susan Landry. Landry told Dr. King that King would never be allowed to work in

the clinical setting. King reminded Landry that she had been promised a clinic time in the newly formed autism clinic. Dr. King further reminded Landry that she had expressed skepticism at the time she took this new position that she could meet the work demands of the position because she was expecting this assignment to the autism clinic. King was told at that time that this could all be worked out and it would not be a problem. Landry replied that the clinic time issue was non-negotiable because Northrup, a close associate of Milewicz, would be required to cross sign King's charts in the clinic for billing purposes. Landry said that Northrup had flatly refused to supervise King in that or any clinic. In a subsequent meeting between King, Landry, Swank and Gasko, Landry proposed that King give up her tenure track forever, stop doing research and even her statistics work on the clinical trial, to devote all her time creating reports to the legislature for the State Center for Early Childhood Development. This proposal meant that King's career would devolve into a data processing, management, analysis, and data interpretation position. During this meeting, Gasko stated that this was a demotion for King from a faculty position to classified staff. Landry suggested at this meeting that the Dean of the medical school of UTHSCH, was putting pressure on Landry about the funding sources for Dr. King's present position. Landry explicitly stated that Dr. Jacqueline Hecht, another close associate of Milewicz and Director of Research for the Department of Pediatrics at UTHSCH, was vocally questioning her about King's continued role on the faculty. Landry told King that she could retain her faculty position if she so chose, but in view of these circumstances it would be "safer" for her to move to the classified staff position. Dr. King was shocked. Without clinical experience and research time, losing her faculty position seemed inevitable and gaining a tenured position would be impossible. This seemed like déjà vu all over again for King. It had been Northrup and Hecht who had consistently blocked King from continuing her tenure track work in 2007, after she was

outed as the complainant against Milewicz. Landry was not offering a choice, this was an ultimatum. Even though this suggested demotion from faculty to administrative staff did not cause any decrease in pay and in fact she was promised a pay raise, it was apparent that the university wanted her to quit. In spite of being presented these bleak options, King was determined to continue to fight for her faculty position and the opportunity to get back on tenure track.

46. Dr. King later met with Landry one on one. In that meeting King and Landry discussed alternative arrangements that would give King an opportunity to retain her faculty position and work toward getting back on tenure track. One alternative discussed was for King to perform a narrower scope of work for the State Center for Early Childhood Development. Since King had been denied access to critical data related to her established area of research, statistical genetic research principally focused on Spina Bifida, and denied an opportunity to participate in the clinical setting, she would now have to find a completely different area of research to build a body of work necessary to get back on tenure track. Landry and King discussed the pros and cons of remaining on the faculty. Landry suggested that King could remain on the faculty if she so chose. Landry agreed that there may be some way for King to restart her research in some other area, thereby satisfying her critics such as Hecht and Northrup, and get back on tenure track. However, Landry did what she could to dissuade King from following this course. Landry warned King that it would be difficult to satisfy some of her faculty evaluators, most of all Hecht, and that her new course of research was progressing satisfactorily. King felt that continuing her research and following her goal and dream to become a tenured faculty member and statistical genetic researcher was too important to abandon.

47. King accepted this new position with the State Center for Early Childhood

Development at UTHSCH on or about January 1, 2010. King moved to her new office only to be told that the raise she had been promised would not be forthcoming. King was told that since she insisted on keeping her faculty position, the offer of a raise had been revoked. King was never told by anyone at UTHSC that if she retained her faculty position, the offer of a raise would be rescinded. King then inquired, taking this new twist into account, if she could give up her faculty position to get the raise. King assumed the answer was no, but asked the question to challenged the obviously pre-textual nature of this reneged illusory offer of a raise. King was right, not only was the offer of a raise now gone, the offer for her to step down from the faculty was gone. King had stepped into UTHSC's snare. Now they had Dr. King right where they wanted her. She was now in a position where her only chance of survival was to impress and please her faculty evaluators, including those who knew she had criticized Milewicz of ethical and regulatory lapses and who were closely associated with Milewicz. She had asked for protection from retaliation and UTHSCH had done nothing in the past. The deck was stacked and King was in a no win situation. Her termination was inevitable and soon to come.

48. In the next several months, King was subjected to sophomoric but effective harassment on the job. She was given conflicting job responsibilities from Landry and Gasko. Her expertise was sought and then ignored. Superiors asked King for research reports and then were dismissed or ignored all together. Critical changes to SCECD programming, essential to the performance of King's job, were made without informing King, compromising the accuracy of her work. Data required for making legislative reports in a timely fashion was not prepared accurately or in a timely manner by staff members responsible for delivering the data to King, forcing her to prepare the data herself, doubling King's workload to meet the legislative reporting deadlines. Training King provided to the team responsible for providing this data was ignored

and never followed in spite of King's multiple efforts to create an effective data management process. King was present at large staff meetings where her programming and data management skills were openly mocked and derided and her insistence on data integrity and accuracy was attacked as setting an unreasonable standard of excellence. The staff was accustomed to an acceptable standard of a 20% error rate prior to her arrival. The data entry was not a difficult task. It included entry of the names of schools, addresses of schools, and other data that simply documented academic levels for Pre-K students. The database was relatively small. Dr. King had discovered that data was entered incorrectly and in some cases, data that was required by legislative mandate was not being captured at all. Dr. King was urging the data management staff to bring this error rate down to 1%. The staff ignored her and her supervisors did not support her efforts and took the position that a 20% error rate was "acceptable". It was not acceptable to King to use this sort of unreliable data as the basis of a report, with her name on it that was to be submitted to the State of Texas. This data collection and the reporting was funded by the State of Texas. King continued to push for better error rates on the data. The more flaws in the data she discovered, the more she was progressively blocked from accessing the inaccurate data sets.

49. In early June 2010, King requested a meeting with Gasko, who was her immediate supervisor. King inquired if she was meeting Gasko's expectations and whether he was happy with her performance. Gasko confirmed that Dr. King was doing a good job and that he was fully satisfied with her performance. Dr. King suggested that she go part time and not perform the reporting function to the State of Texas because she was uncomfortable with the accuracy of the underlying data. This was not the first time Dr. King had discussed her concerns about the underlying data with Gasko. Gasko did not reply and abruptly ended the meeting.

50. The following week, in a meeting discussing the data integrity issue, Swank's data management group affirmed their position that a 20% error rate was acceptable. Swank and his group also were comfortable with not capturing legislatively mandated data they were being paid by the state to collect. Swank was present at this meeting and did not object to this dismal standard of accuracy. Dr. King responded that she did not find a 20% error rate acceptable, nor the lack of legislatively mandated data collection. If that was the best King could expect from the data managers in Swank's group, she would prefer to manage the data herself. At that point Swank angrily left the meeting, slamming his chair against the wall and stating that Dr. King's insistence on excellence was unreasonable. Later that week, Swank and Gasko called Dr. King into a conference and they informed her that King's contract would not be renewed. Gasko and Swank informed her that her last day with the University would be August 28, 2010.

51. It was agreed that Dr. King would complete two projects that were underway related to processes and computer programs designed to manage and analyze data. In the course of completing these projects, King discovered that some previously collected data that had already been submitted to the State of Texas was extremely inaccurate, with error rates in the 50% - 90% range. King presented this data problem to Gasko and showed him the basis of her conclusion. Gasko conferred with Landry and Swank on this problem and they confirmed that the inaccurate data had indeed been submitted to the State of Texas. Gasko told King that they had confirmed that this data that had been sent to the State of Texas and had very high error rates and that somehow this data had been "replaced" in the State of Texas data banks. Gasko then told King that she was not to access this data in the future, cut off her access to this data and told her to sit in her office until her last day came to pass.

52. When King asked Gasko why her contract was not renewed, he said, "it was less

about your complaints about data integrity and more about your history". When King asked what he meant when he said "your history", Gasko responded by saying he didn't want to speak for Karen Parsons or the University on that subject. Parsons was General Counsel to the compliance office at UTHSC. King had never told Gaskow about her "history" with the UTHSCH compliance office. If Gasko knew about her "history", it could only mean that her confidentiality as a person who had reported scientific misconduct had again been breached.

53. Four (4) days before King left UTHSCH, she was invited to a Committee for the Protection of Human Subjects. Special Meeting of the IRB Panel #1. King was still a member of this IRB panel committee and was still on the distribution list. (Ex. 57, email, Romo to King, August 16 2010) Ironically, the purpose of the meeting was to discuss the final findings of the investigation into Milewicz's non-compliance with regulatory requirements mandating written informed consent from participants in her human studies. King received the packet of information related to the meeting. The packet of information included an admission by Milewicz that she had not complied with regulatory procedures regarding obtaining consent from her human subjects. (Ex. 58, Milewicz to Dougherty, August 13, 2010) Milewicz admitted to failing to obtain and keep on file proper documentation of consent for over one hundred of the human participants in studies that formed the basis of Milewicz's publications. (Ex. 58) Milewicz admitted that there were 289 missing consent forms regarding samples in her DNA bank. Milewicz admitted that in 160 non-familial samples, the consent forms were missing or defective in some fashion that violated federal regulations. Milewicz admitted that the required consenting procedure had not been properly followed for 129 familial samples. This represents widespread, ongoing, serious misconduct in the world of human subject research. UTHSCH promised, in exchange for the right to seek federal dollars for research, that they would perform

the oversight function to be sure that this sort of breach of federal standards would not happen, or if it did, take action to stop the continuing breach.

54. King emailed Anne Doherty, Executive Director of the IRB at UTHSCH, and Richard Kirkedee, Chair of IRB Committee #1, and asked their opinion as to whether or not King should attend the ad hoc meeting regarding Dr. Milewicz. Doherty recommended that Dr. King not attend. Kirkedee did not respond. King packed her things and left her career and hopes of ever being a tenured professor in her chosen field behind. Milewicz is still performing research, funded by federal dollars, at UTHSCH.

**V.  
SUBSTANTIVE COUNTS  
COUNT ONE**

**Fraud Against the Government**

55. The allegations contained in paragraphs 1-54 are incorporated herein and alleged as if fully set forth below.

56. The actions set out above on the part of UTHSCH, were not inadvertent or accidental but, on the contrary, were carried out knowingly and were calculated to defraud the United States Government. The actions of the Defendant constitutes false claims in violation of 31 U.S.C. §§ 3729 *et seq.*

57. UTHSCH, by and through its officers, agents, supervisors and employees, knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States Government, all as alleged above, and specifically with regard to the federally funded research.

58. UTHSCH, by and through its officers, agents, supervisors and employees falsely certified to the federal government, in exchange for the right to apply for and obtain federal



funding for human research that they would abide by and were abiding by the federal regulations governing research utilizing human subjects. UTHSCH falsely certified that they would abide by and were abiding by federal regulations regarding obtaining informed consent from human subjects. UTHSCH, acting through its officers, agents, supervisors and employees failed to abide by the regulations governing the methods and record keeping regarding informed consent of human subjects. The award of any federal grant for human research requires that institutions such as UTHSCH abide by all informed consent federal regulations. UTHSCH falsely certified that it would maintain and had in place a system of oversight that would fully investigate allegations of research misconduct. The award of any federal grant for human research requires that an institution such as UTHSCH have in place an oversight committee and that all allegations of research misconduct be fully investigated and all findings be reported to the investigating agencies. UTHSCH failed to fully investigate and fraudulently covered up research misconduct by Milewicz in an effort to allow her and other researchers full access to federal grants for research. UTHSCH falsely certified that it would not retaliate against any person who came forward and made a report of research misconduct at UTHSCH. Federal regulations prohibit retaliation against persons who come forward and report research misconduct. The award of any federal grant for research requires that an institution certify that it has not and will not retaliate against any person who makes a report of research misconduct. UTHSCH retaliated against Terri King and other employees of UTHSCH who made reports of research misconduct on the part of Milewicz. UTHSCH failed to report that they had retaliated against King and other employees to protect Milewicz and other UTHSCH researcher's opportunity to seek and obtain federal funding for research.

59. As a proximate and direct result of the aforesaid illegality set out above, the United States of America has been defrauded of substantial sums of money, and Defendant is liable to the United States for said sums together with all applicable penalties and interest.

60. Having brought this civil action on behalf of the United States of America, and having met all other prerequisites set out in 31 U.S.C. § 3730, King is entitled to an award of 30% of the proceeds of this action collected by the United States of America as a result of King's institution of this action plus an amount for reasonable expenses necessarily incurred and reasonable attorney's fees and costs.

#### **IV. SUBSTANTIVE COUNTS COUNT TWO**

##### **King's Private Action for Retaliation and Wrongful Termination**

61. The allegations contained in paragraphs 1-54 are incorporated herein and alleged as if fully set forth below.

62. King was an employee of UTHSCH at the time she reported research misconduct regarding Milewicz. UTHSCH, by and through its officers, agents, supervisors and employees, retaliated, in violation of federal regulations prohibiting said retaliation, against King as a result of her report of research misconduct. UTHSCH demoted King in retaliation for her reports of research misconduct. UTHSCH derailed any chance of King becoming a tenured member of the faculty at UTHSCH in retaliation for her reports of research misconduct. UTHSCH ultimately terminated King as a result of her reports of research misconduct. As a proximate result of this illegal retaliation, King has suffered lost earnings in the past and in reasonable probability will suffer lost earnings and lost earning capacity in the future. As a proximate result of UTHSCH's retaliation, King has suffered humiliation and mental torment in the past and will in reasonable

probability suffer same in the future. King hereby asserts a cause of action for wrongful termination seeking all damages allowed by law and attorney's fees for the prosecution of this case including but not limited to the remedies afforded by U.S.C.A. §3730 (h)(2).

WHEREFORE, King prays on behalf of the United States of America and herself that Defendants be cited to appear and answer, and that following Trial of this cause, that Plaintiff United States of America ex rel. Terri King, have and recover the following relief from Defendants:

- a. all damages sustained by the United States of America as a result of Defendants' violations of 31 U.S.C. §§ 3729 *et seq.*;
- b. statutory penalties in the amount of \$10,000 for each false claim plus three times the amount of damages which the United States of America has sustained because of the wrongful acts of Defendants;
- c. forfeiture of all moneys sought and/or secured through false claims directly or indirectly submitted by Defendants to the United States of America; and
- d. such other and further relief to which the United States government may show itself justly entitled including court costs.


MOREOVER, Terry King, individually and on her own behalf prays that following trial of this cause she have and recover the following relief:

- a. thirty percent (30%) of the proceeds collected by the United States as a result of this action, plus an amount for reasonable expenses necessarily incurred plus reasonable attorney's fees and costs;

- b. back pay, front pay and related damages as plead above resulting from the wrongful retaliation and or termination of King;
- c. such other and further relief to which King may show herself justly entitled.

Respectfully submitted,

**THE KIM LAW FIRM**

/s/ John H. Kim 

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